MDMA MEDICAL DEVICE MANUFACTURERS ASSOCIATION

November 1, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, Maryland 20852

Re: Docket No. 99D-2212 -- Guidance on Quality System Regulation Information for Various Premarket Submissions

Dear Sir or Madam:

The Medical Device Manufacturers Association (MDMA) appreciates this opportunity to comment upon the draft guidance entitled "Guidance on Quality System Regulation Information for Various PreMarket Submissions," published and made available by the FDA on August 3.

MDMA is the national voice for the entrepreneurial sector of the medical technology industry and represents 130 independent manufacturers of medical devices, diagnostic products, and health care information systems. As such, MDMA seeks to improve the quality of patient care by encouraging the development of new medical technology and by fostering the availability of beneficial innovative products to the marketplace.

The draft guidance suggests that certain elements of the FDA's Quality System (QS) regulation (21 CFR part 820) are "requirements" for premarket approval of medical devices. For instance, on page 3 of the draft guidance, the FDA asserts the following:

> PMA and PDP submissions should include a complete description of design controls and manufacturing information required by the QS regulation. This information should be included in standard PMA's, modular PMA's, streamlined PMA's, and PMA supplements. Without this information, the premarket review process for these devices cannot be completed [emphasis added].

In addition, the draft guidance appears to establish a variety of substantive design-control requirements that go beyond those set out in the current QS regulation.

The FDA, pursuant to section 520(f)(1)(A) of the FD&C Act, has promulgated specific design-control requirements to which manufacturers of PMA, PDP, and 510(k) devices must adhere under the QS regulation. While the FDA may believe that many of the items in the draft guidance are good practices for implementing a quality system, these items simply are not required under the QS regulation.

The following provisions in the draft guidance do not specifically appear in the QS regulation:

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Item 1 – there is no specific requirement in 820.30(a) to provide an explanation of when design controls apply.

Item 2 – there is no specific requirement in 820.30(a) to describe how risk management or risk analysis will be used throughout the design and development of the device.

Item 3 – there is no specific requirement in 820.30(b) for the design and development plan to include information on the development strategy or to outline the timing strategy, deliverables and milestones that must be completed before the initiation of certain tasks.

Item 4 – there is no specific requirement in 820.30(c) to include a copy of the written procedure for the identification and control of design input addressing intended use, user/patient/clinical (interfaces and inputs), performance characteristics, safety characteristics, limits and tolerances for safety and performance parameters, risk analysis, toxicity and bio-compatibility, electromagnetic compatibility, compatibility with accessories/auxiliary devices, compatibility with the environment of intended use, human factors, physical/chemical characteristics, labeling/packaging, reliability, statutory and regulatory requirements, voluntary standards, manufacturing processes, sterility, MDRs/complaints/failures and other historical data, past design history files (DHFs), year 2000 problems for computerized devices and computerized interfaces.

Item 5 – there is no specific requirement in 820.30(c) to summarize how user interface and other human factors issues are considered and addressed in the design input.

Item 6 – there is no specific requirement in 820.30(c) to provide for electronically powered devices an explanation of how EMC issues are considered and addressed in the design inputs.

Item 9 – the second bullet exceeds the requirements in 820.30(f) as there is no specific requirement for a procedure to contain or make reference to a process for resolving any discrepancy between design output and design input requirements.

Item 15 – there is no specific requirement in 820.30(g) for a summary of the risk management program that describes how and when risk management was and will be performed, including how the results of the risk management process will be documented, used, and updated.

Item 19 – the first bullet exceeds the requirements in 820.30(j) as there is no specific requirement that, if more than one device shares a common DHF, there should be a procedure that describes how the manufacturer identifies each device within the family or group having common characteristics.

In addition, the draft guidance's directive that a Design Control Dossier, a Manufacturing Dossier or a quality manual or other documentation should be consistent with ISO 10013-1195 exceeds the requirements of the QS regulation. If FDA wants the requirements of ISO 10013-1195 to be legal requirements, the agency should commence notice-and-comment rulemaking on this point.

MDMA Position

In establishing new content requirements for PMA and PDP submissions and new design-control requirements under the QS regulation, the FDA is imposing specific duties on manufacturers. The guidance process is not the appropriate mechanism for such action. The development of such requirements should only be accomplished through the rulemaking process. This will ensure that the agency considers whether these additional burdens are necessary.

Therefore, MDMA respectfully recommends that the FDA withdraw this draft guidance document. MDMA believes this draft guidance, if implemented, would add to manufacturers' regulatory burden without contributing meaningfully to the protection of the public health or patient safety. FDA investigators are already charged by law with evaluating design-control and related information during FDA inspections for compliance with the QS regulation. Having premarket-review officials also learn the QS regulation and check the procedures that a manufacturer has established for design controls is redundant and wastes agency resources. During an era in which the FDA asserts that its resources are limited, the agency should not have personnel in different offices perform duplicative functions.

Thank you for this opportunity to comment.

Very sincerely yours,

Stephen J. Northrup
Executive Director

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